



NAME: CAPT (RETIRED) ROBBIN M.
NIGHSWANDER

JOB TITLE: SUPERVISORY REGULATORY
HEALTH PROJECT MANAGER

AGENCY: FOOD & DRUG ADMINISTRATION
(FDA)

EDUCATION/DEGREES/CERTIFICATES/INSTITUTIONS:

Captain (Retired) Robbin Nighswander obtained a Bachelor of Science in Pharmacy from Ferris State College in Big Rapids, Michigan in 1971. Next, he completed a Hospital Pharmacy Residency Certification Program through the American Society of Hospital Pharmacy at the United States Public Health Service (USPHS) Hospital in New Orleans, Louisiana in 1972. CAPT Nighswander then worked as Chief Pharmacist for six years at the USPHS Outpatient Clinic in Savannah, Georgia. Later, he returned to academics at the University of Minnesota in Minneapolis where he was awarded a Masters of Science in Social and Administrative Pharmacy in 1979.

CURRENT JOB DESCRIPTION:

CAPT Nighswander's current position as the Supervisory Regulatory Health Project Manager for the FDA, Center for Drug Evaluation (CDER), Office of Drug Evaluation I, Division of Neurology Products is noteworthy in terms of his responsibilities and accomplishments. As Chief of the Division's Project Management Staff, he provides regulatory and administrative support to multidisciplinary teams during the review of Investigational New Drug Applications (INDs), New Drug Applications (NDAs), and Biologics License Applications (BLAs). He provides expert consultation to the Division Director as well as to medical and scientific staff on issues involving the Federal Food, Drug, and Cosmetic Act. An important component of his job involves familiarity with the laws that govern the drug approval process and he frequently identifies policy issues and resolves complex regulatory problems. Along with providing supervision, leadership and guidance for 11 regulatory project managers, he represents the Division during meetings with industry and other governmental agencies. CAPT Nighswander is also the Division's focal point in responding to information requests from FDA's Commissioner's Office as well as Health and Human Service's Office of General Counsel.

QUALIFYING SKILLS FOR CURRENT POSITION:

CAPT Nighswander's skills are a culmination of commitment and self-directed accomplishments during his 20+ years of service with the FDA (17 years as an active duty PHS officer followed by civilian service after retirement), his academic background, as well as his previous PHS assignments. Before obtaining his current position as Supervisory Regulatory Health Project Manager, CAPT Nighswander started with the

Division of Neuropharmacological Drug Products as a Consumer Safety Officer (Project Manager) from 1984-1990. His responsibilities included acting as the liaison between regulated firms or independent researchers who submitted INDs and NDAs for neurologic and psychopharmacologic drug products. He developed a regulatory training/mentoring program for Consumer Safety Officers within the Division which was eventually expanded to include newly employed Clinical Review Staff as well. From 1990-2001, CAPT Nighswander obtained a position as Senior Regulatory Management Officer/Team Leader. His responsibilities expanded as the lead regulatory project manager for the entire Division. His duties included planning, coordinating, training, mentoring, assigning work, and reviewing product quality for the division's regulatory project management staff. He acted as senior regulatory consultant to the Division Director and continually assured that the Project Management staff stayed abreast of new regulations and policies.

REASONS FOR CHOOSING THE USPHS AS A CAREER:

As with many officers who entered the USPHS at the time, the USPHS provided an attractive mechanism for fulfilling Selective Service Requirements. Once on Active Duty, the wide variety of professional experience opportunities and the quality of pharmacy services provided by the PHS convinced young Lieutenant Nighswander to consider PHS Pharmacy as a career.

PREVIOUS USPHS ASSIGNMENTS:

- 1972-1978: Chief Pharmacist, Outpatient Clinic, Savannah, GA: Also responsible for pharmaceutical services at both the Atlanta, GA CDC outpatient clinic and the Charleston, SC outpatient clinic.
- 1979-1980: Deputy Chief Pharmacist, USPHS Hospital, Boston, MA: Supervisory role, redesigned the inventory management system and purchased all equipment and supplies. Deployed for 2 weeks to Ft. McCoy, WI to provide pharmaceutical services for Cuban refugees.
- 1980-1982: Deputy Chief, USPHS Hospital, Nassau Bay, TX: Supervised development of pharmaceutical systems for the 1st three NASA Space Shuttle flights.
- 1982: 3-month detail to the Sister's of Charity of the Incarnate Word, Nassau Bay, TX: Established a Pharmacy Department in a newly created hospital after closure of the USPHS Hospital in Nassau Bay.
- 1982-1984: Chief Pharmacist with the USPHS Indian Hospital in Zuni, New Mexico. Established a computer based pharmacokinetic dosing program for aminoglycoside antibiotics.
- 1984-1990: Consumer Safety Officer in the Division of Neurologic and Psychiatric Drug Products.
- 1990-2001: Senior Regulatory Management Officer/Team Leader, Division of Neurological Drug Products.
- 2001-present: Supervisory Regulatory Health Project Manager, Division of Neurology Products.

MOST REWARDING USPHS PROFESSIONAL EXPERIENCE:

This is a most difficult question to answer as all of the PHS pharmacy experiences were rewarding. What stands out was having been provided the opportunity to provide direct pharmaceutical services to a wide variety of American citizens including: American Seaman, Active and Retired Uniformed Service Members, astronauts, American Indians, and several refugee groups. Later in my career, while at the FDA, CAPT Nighswander was afforded the opportunity to help those afflicted with Alzheimer's disease, various drug addictions, and the development and approval of treatments intended to counter the effects of chemical nerve agents.

One particular 4 day experience is rather poignant and occurred while being transferred from the Nassau Bay, TX hospital to the Zuni Indian Health Hospital in New Mexico. His last Friday at the Nassau Bay hospital was spent orienting the Sisters' of Charity on how to prepare pharmaceuticals for use by astronauts on the Space Shuttle. Upon arrival in Zuni the following Monday, CAPT Nighswander was dispensing medication and providing patient counseling to older Native Americans who spoke only in their Native language. What struck him was the wide variety of opportunities to provide excellent pharmacy services that's available to PHS pharmacists regardless of the socio-economic status of those being served.

By CDR Elizabeth Girard